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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
TURNER, SHARON L	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 12/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/788,666	SCHENK, DALE B.	
	Examiner	Art Unit	
	Sharon L. Turner	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,38,54-60,62-65,67-72,74-82,85-89 and 91-97* is/are pending in the application.

4a) Of the above claim(s) *1,38,54,55,74,75 and 93-97* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *56-60,62-65,67-72,76-82,85-89,91 and 92* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

SDD

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,38,54-60,62-65,67-72,74-82,85-89 and 91-97.

DETAILED ACTION

1. The Examiner and/or Art Unit of this patent application has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to Examiner Turner, Technology Center 1600, Art Unit 1649.

2. The amendment filed 7-12-05 has been entered into the record and has been fully considered.

3. Claims 1, 38, 54, 55-60, 62-65, 67-72, 74-82, 85-89 and 91-97 are pending.

Election/Restrictions

4. Applicant's election of Group IV, claims 56-60, 62-65, 67-72, 76-82, 85-89 and 91-92 in the reply filed on 7-12-05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1, 38, 54, 55, 74-75, 93-97 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7-12-05.

Specification

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Priority

6. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied

with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) and 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for the claims of this application. In particular for base claims 56, 76-81 and dependent claims 57-60, 62-65, 67-72, 74, 82, 85-89 and 91-92. Instant claims are directed to; (claim 56) A method for effecting rapid improvement of cognition in a subject having a condition or disease related to Abeta, comprising administering to the subject an effective amount of an anti-Abeta antibody, (claim 76) A method for treating cognitive symptoms of a condition or disease associated with Abeta in a subject, comprising administering to the subject an effective amount of an anti-Abeta antibody that has greater affinity for soluble Abeta than 10^{-9} M, (claim 77) A method for reducing disease progression in a subject having a condition or disease associated with Abeta, comprising administering to the subject an effective amount of an anti-Abeta antibody that has greater affinity for soluble Abeta than 10^{-9} M, (claim 78) A method for improving cognitive symptoms of a condition or disease associated with Abeta in a subject comprising administering to a subject an effective amount of an anti-Abeta antibody that has affinity (KD) for soluble Abeta1-40

or Abeta1-42 higher than 10^{-9} M, (claim 79) A method for reducing disease progression in a subject having a condition or disease associated with Abeta, comprising administering to the subject an effective amount of an anti-Abeta antibody that has affinity (KD) for soluble Abeta1-40 or Abeta1-42 higher than 10^{-9} M, (claim 80) A method for improving cognitive symptoms of a condition or disease associated {with} Abeta in a subject comprising administering to a subject an effective amount of an anti-Abeta antibody that has greater affinity for soluble Abeta than antibody 266 has, (claim 81) A method for reducing disease progression in a subject having a condition or disease associated with Abeta, comprising administering to the subject an effective amount of an anti-Abeta antibody that has greater affinity for soluble Abeta than antibody 266 has. However, support for these limitations is not found particularly to "rapid improvement of cognition", "treating cognitive symptoms" and treatment of "mild cognitive impairment" as claimed. Moreover, the subgeneric population of antibodies defined by affinity for soluble Abeta and affinity for antibody 266 or humanized antibody 266 are not noted to be found. Accordingly, the effective filing date awarded instant claims is that of the instant filing date of 2-27-04 absent evidence for particular support within the priority documents.

Claim Objections

7. Claims 58, 60, 68, 70, and 91-92 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 58, 60 and 92 fail to further limit as "mild cognitive impairment" is not recognized as a

condition or disease related to beta amyloid. For example, consider that cognitive impairment may be prevalent upon a concussion, not related to Abeta. Similarly, "vascular dementia" may be prevalent in stroke, not related to Abeta. Accordingly, the limitation is deemed to further broaden the disease populations as recited. Claim 68 broadens claim 67 as it recites "an analog thereof" and therefore broadens from the previous antibody. It is unclear how claim 70 is intended to further limit the affinity with respect to the recitation of measurement with respect to Abeta 1-40 or 1-42 where such are not stipulated as soluble and are recognized as aggregating forms.

8. Claims 85-89 and 91-92 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot serve as the basis for another multiple dependent claim. Here claim 82 depends from multiple claims and is alos referred to in claims 85-59 and 91-92 as multiply dependent. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits. The Examiner has attempted to denote certain other deficiencies of the claims where possible.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 56-60, 62-65, 67-72, 74, 76-82 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims164-167 and 198-199 of copending Application No. 10/923,927, claims 151-157 of copending Application No. 10/923,469, claims 164-168, 171, 174 and 183 of copending Application No. 10/923,267 and claims 84-86 of copending Application No. 10/828,548. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Instant claims are generically directed to treatment of cognition via administration anti-Abeta antibodies. The noted co-pending applications are similarly directed to cognition treatment where the administration is of anti-Abeta antibodies. It is further noted that the co-pending applications specify epitope 13-28 of beta amyloid disclosed as corresponding to mab266 evidenced as having 10-9 M affinity to beta-amyloid. Accordingly, patenting of the co-pending claims would serve to anticipate instant claims directed to such limitations and which are either generic or similarly directed.

The Examiner notes that the instant case shares the same inventor and common subject matter with over 100 applications currently under prosecution before the PTO.

Applicants share in their duty to disclose relevant information pertaining to any co-pending applications where prosecution may amend claims such that they may be drawn to common subject matter and/or are subject to either statutory or nonstatutory double patenting rejections.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 56-60, 62-65, 67-72, 76-82, 85-89, and 91-92 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while exhibiting reduced beta-amyloid deposition levels in vivo following administration of polyclonal anti-Aβ, mAb 10D5 (anti-Aβ1-16), mAb 266 (anti-Aβ13-28), and mAB21F12 (anti-Aβ33-42) as disclosed at pp. 76 for six months as measured via ELISA analysis of plaque burden as noted in Tables 11-13, does not reasonably provide enablement for effecting rapid imiprovement of cognition in a subject, for treating cognitive symptoms of a condition or disease associated with Abeta in a subject or for reducing disease progression in a subject having a condition or disease associated with Abeta. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected to make and use the invention commensurate in scope with these claims.

The specifications disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without undue experimentation. The factors

relevant to this discussion include the quantity of experimentation necessary, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims.

The specification teaches that the administration of particular antibodies is able to reduce beta-amyloid levels within the brains of mice which are transgenic for PDAPP. These mice exhibit Alzheimer type over production and build up of beta-amyloid within the brain. However, as recognized in the art, these mice do not exhibit Alzheimer's disease as in humans or plaque morphology and components which are exactly the same as in humans, Alzheimer's disease, Down's Syndrome or other amyloidogenic diseases, see in particular Schenk et al., Nature, 400:173-77, 1999, Games et al., Nature 373(6514):523-7, 1995 and Chen et al.; Progress in Br. Res., 117:327-34, 1998 noting particularly the differences in paired helical filament formation and plaque progression coincident with degenerative changes in Alzheimer's patients.

The instantly claimed method is based upon findings which show particular strategies of targeting plaque removal via antigen or antibody administration. Evidence that such therapy may be effective in the removal of amyloid plaque burden is exhibited by Lemere et al., Society for Neuroscience Abstracts, vol. 25, part I, Abstract 519.6, 29th Annual Meeting 10/23-10/28, 1999, and Schenk, Nature, 400:173-177, 1999 using antigen and DeMattos, PNAS 98(15):8850-8855, 2001 using antibody administration. However, none of these references support that such treatment is effective to provide for treating cognitive symptoms, effecting rapid improvement in cognition or reducing disease progression (cognitive decline for example) in Alzheimer's disease. Alzheimer's is a disease characterized by progressive impairment of cognitive function

amongst other pathological hallmarks, see in particular Auld, Progress in Neurobiology, 68:209-245, 2002 for which there is currently no definitive treatment or cure, see also Parnetti et al., Drugs, 53(5):752-68, 1997.

The scope of instant claims directed to diseases related to Abeta is broader than Alzheimer's and is inclusive of for example cognitive dysfunction amyloid deposition associated diseases including prion disease, type II diabetes and pancreatic amyloidosis. Such diseases differ in etiology, pathology and effects. For example, Down's syndrome is caused via trisomy, type II diabetes via insulin dysregulation and/or non-responsiveness and prion disease via prion protein, see in particular Kayed et al., J. of Mol. Biol., 287(4):781-96, 1999.

Cognitive impairment may be induced via a host of genetic and environmental cues ranging from trauma to retardation as noted in Down's syndrome or trisomy individuals. Yet the instant model system is based on a gene mutation observed in individuals predisposed to Alzheimer's disease. The PDAPP model is not based upon and fails to address the etiology or pathology of alternative amyloid deposition diseases in brain other than Alzheimer's plaque deposition. Thus the PDAPP model is not recognized as being of commensurate scope for, or useful in, predicting treatments for cognitive impairment. Yet even so, neither the art nor the specification teach improvement of any facet related to cognition within the PDAPP mouse via anti-Abeta antibody administration. The art does recognize as briefly summarized at p. 225-227 of Auld, 2002 that cognitive deficits are noted in some art recognized mouse models of Alzheimer's disease including the PDAPP mouse. Yet none of these references evidence, teach or recognize that anti-Abeta antibody treatment is effective to improve

cognitive function in such animals. Morgan et al., Nature 408 :982-985, 2000 is most relevant where at a post-filing date Morgan evidences that peptide vaccination may prevent memory loss in animal models transgenic for APP or APP and PS1 expression. However, even Morgan does not evidence treatment of cognition via antibody administration. Thus, neither the specification nor the art even at a post-filing date recognize enablement commensurate in scope with the invention claimed.

The claims are directed to administration of an "effective dosage". Yet the specification does not teach any exemplification of an effective does to treat or improve cognition or to reduce progression (of cognitive decline associated with Alzheimer's disease) as claimed. Moreover, there are no means presented for ascertaining how such doses should be determined. The instant situation is directly analogous to that which was addressed in *In re Colianni*, 195 U.S.P.Q. 150,(CCPA 1977), which held that a "[d]isclosure that calls for application of "sufficient" ultrasonic energy to practice claimed method of fusing bones but does not disclose what "sufficient" dosage of ultrasonic energy might be or how those skilled in the art might select appropriate intensity, frequency, and duration, and contains no specific examples or embodiment by way of illustration of how claimed method is to be practiced does not meet requirements of 35 U.S.C. 112 first paragraph". In particular the "effective dosage" is to be administered to the patient so as to provide improvement, treatment or reduction in progression related to cognition. Yet the recitation fails to note the particular symptoms, pathology or effects and their means of being alleviated or treated.

Thus, applicants have not provided sufficient guidance to enable one skilled in the art to make and use the claimed derivatives in a manner reasonably correlated with

the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without such guidance, the changes which can be made and still maintain activity/utility is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Int. 1986).

In view of the quantity of experimentation necessary, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue experimentation to make and use the claimed invention.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 56-60, 62-65, 67-70, 76-82, 85-89, and 91-92 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,688,651 Solomon et al., Nov. 18, 1997 as evidenced by Seubert, Nature 359:325-327, 1992 or in the alternative as obvious over US 5,688,651 Solomon et al., Nov. 18, 1997 as evidenced by Seubert, Nature 359:325-327, 1992.

Solomon et al., teach treatment of Alzheimer's disease and prevention of beta amyloid protein aggregation in patients having such thereby fairly teaching the notable administration to patients with Down's syndrome and cognitive impairment as a result of

such aggregation of amyloid via administration of anti-aggregating amyloid antibodies. In particular, Solomon directs that the antibodies should be specific to beta amyloid and include preferred antibodies reactive to epitope 1-28. Solomon further directs that the antibodies include those reactive to epitope 25-28 of beta amyloid and that this is an epitope or locale directing anti-aggregating properties, see in particular columns 2-3, 6, 11-12 and 15-16, especially column 6, lines 21-26, and 16, lines 5-14. Preferred antibodies include AMY-33 raised to epitope 1-28 and 6F/3D raised to epitope 8-17, the same epitope as mab266, Seubert, Nature 359:325-327, 1992 (formed agains epitope 13-28. Detailed Description Text (13):In the preferred embodiment the human monoclonal antibody that binds to an aggregating protein and which prevents aggregation is utilized. In a further preferred embodiment the monoclonal antibody is an anti-.beta.-amyloid and is designated AMY-33 which recognizes amino acids 1-28 of .beta.-amyloid. Solomon further notes the inclusion of antibodies that are single chain or engineered including antibody fragments, see in particular column 16, particularly lines 27-37. The Solomon reference teaches that the quantity of antibody should be of equal molar ratio of antibody/antigen for binding, see column 13 and as via ELISA assay, see example 2. The reference also notes that the quantity to be administered is to be effective to inhibit aggregation of beta-amyloid in the host. Accordingly the reference is enabling for quantities that are effective at inhibiting and/or preventing aggregation.

With respect to the claims, the preamble is akin to a statement of "intended use" i.e., "for effecting rapid improvement of cognition/treating cognitive symptoms/reducing disease progression in a subject having a condition or disease related to Abeta" and does not receive distinguishing patentable weight outside limitation within the claim

body that distinguishes the administration from another. In this respect, it is noted that as directed in MPEP 2112, SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLEUPON THE DISCOVERY OF A NEW PROPERTY*>"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the< claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims and MPEP § 2141.02 with regard to inherency and rejections under 35 U.S.C. 103.a met.

The Examiner is not in a position to discern whether the quantities of Solomon are inherently the same or obvious to those amounts that are "an effective amount" as claimed, as the PTO does not have sufficient resources to determine such. Similarly, the Examiner has insufficient resources to determine if the antibodies of the prior art, have affinity for soluble beta-amyloid greater than 10-9M, greater affinity than humanized antibody 266, 10-10M, or greater affinity when measured with respect to Abeta 1-40 or 1-42. It is noted that the antibodies recognize the same epitope that antibody mab266 recognizes and therefore competes for binding to soluble Abeta, note epitope specificity of 1-28, 13-28 and comprising epitope of amino acids 25-28 which are the anti-aggregating antibodies as specified in column 16, lines 5-10 of '651 patent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 56-60, 62-65, 67-72, 76-82, 85-89, and 91-92 rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,688,651 Solomon et al., Nov. 18, 1997, US 6,787,138 Schenk Sept. 7, 2004, Younkin, "Amyloid .beta. vaccination; reduced plaques and improved cognition," Nature Medicine, 7:18-19 (2001) and Seubert et al., Nature 359:325-327, 1992.

Solomon et al., teach as set forth above. In particular Solomon teaches treatment of Alzheimer's disease and prevention of beta amyloid protein aggregation via administration of anti-aggregating amyloid antibodies. In particular, Solomon directs that the antibodies should be specific to beta amyloid 1-28 and further direct that antibodies reactive to epitope 25-28 of beta amyloid are the locale for the anti-aggregating antibodies, see in particular columns 2-3, 6, 11-12 and 15-16, especially column 6, lines 21-26, and 16, lines 5-14.

Seubert et al., teach as set forth above, in particular antibody mab266 specific to epitope of beta amyloid 1-28 comprising anti-aggregating antibody epitope 25-28.

One of skill in the art would be motivated to administer mab266 to patients as directed by Solomon given that the antibody is noted to be specific to the anti-aggregating epitope comprising amino acids 25-28. One of skill in the art would have expected success via such administration given the antibody was generated to the anti-aggregating eptiope.

Neither Solomon or Seubert teach measuring cognition either before or after administration.

Schenk et al., teach treatment of Alzheimer's and Down's syndrome via administration of either epitopes of Abeta including residues 13-28 to stimulate an immune response or antibody mab266.

Younkin, "Amyloid .beta. vaccination; reduced plaques and improved cognition," Nature Medicine, 7:18-19 (2001) teaches that administration of antibodies or antigen administration via beta amyloid vaccination is known to reduce plaques synonymous with the treatment via Schenk. Younkin further teaches that such administration should be evaluated for its relevance to improvements in cognition via a variety of animal models to evaluate the effectivness of such treatments to improve cognition whereby measurement of cognition is performed either before and/or after administration of antigen/antibody, see in particular pp.18-19.

Thus, one of skill in the art would be motivated to evaluate the treatment for cognitive improvement as suggested via Younkin. One of skill in the art would have an expectation of success in performing such analysis as Younkin teaches such animal models are useful and provide insight to the effectiveness of antigen/antibody administration in treatments for Alzheimer's disease, in particular for evaluation of removal of amyloid plaques in addition to effects on cognitive performace. Thus, the cumulative reference teachings render obvious the steps of analysis via in vivo models, before during and after administration of antigen comprising anti-aggregating eptiopes and/or antibody specific to such anti-aggregating eptiopes.

Conclusion

16. No claims are allowed.

17. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (571) 272-0894. The examiner can normally be reached on Monday-Thursday from 7:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached at (571) 272-0867.

Sharon L. Turner, Ph.D.
October 17, 2005